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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,283	09/27/2000	John A. Giordano	22920.0003	6590

23767 7590 03/12/2002  
MCKENNA & CUNEO, LLP  
1900 K Street, NW  
Washington, DC 20006

EXAMINER
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BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/12/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/671,283

Applicant(s)

GIORDANO ET AL.

Examiner

Mojdeh Bahar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) 53-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's response to the restriction requirement submitted 2/21/02 is acknowledged.

Applicant's election with traverse of the invention of Group I in Paper No. 4 submitted 02/21/02 is acknowledged. Applicant's traversal has been considered but is not persuasive.

Applicant argues that the search for all claims (1-116) is no undue burden for the office. As discussed in the Restriction Requirement of 01/22/02 the two Groups are drawn to two patentably distinct invention, see particularly page 2 of the Restriction Requirement. Note that the search is not limited to patent files. The search field for a composition is different from the search field for a particular method of use employing the same composition ingredients.

Because the considerations as to patentability are individual to each Group herein and the burden of search for all inventions is undue, as discussed herein and in the restriction requirement, the restriction requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 53-116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 4.

Claims 1-52 are herein examined on the merits.

### ***Claim Objections***

Claims 2-13, 39-40 and 42-52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent

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form, or rewrite the claim(s) in independent form. Note that the recitation of intended use, regimen and/or host does not further limit a claim drawn to a composition.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 contains the trademark/trade name L-Optizinc ZML-200 InterHealth. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe zinc and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-13, 20, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Centrum.

Centrum discloses a composition comprising Vitamin C, Vitamin E, chromium, Selenium, Zinc and B-complex (20 mg of niacin, vitamin B6 or pyroxidine, thiamin, riboflavin, vitamin B12 or Cyanocobalamin, 10 mg of pantothenic acid, folic acid and biotin).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 14-19, 21-22, 24, 26-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Centrum in view of GNC Ultra Mega Green.

Centrum discloses a composition comprising Vitamin C, Vitamin E, chromium, Selenium, Zinc and B-complex (20 mg of niacin, vitamin B6 or pyroxidine, thiamin, riboflavin, vitamin B12 or Cyanocobalamin, 10 mg of pantothenic acid, folic acid and biotin).

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Centrum does not teach the particular forms of Vitamin C, E, and B-complex, neither does it teach the particular salts of Chromium, Selenium and Zinc. Centrum does not teach the particular amounts of vitamin B6 or pyroxidine, thiamin, riboflavin, vitamin B12 or Cyanocobalamin, folic acid, biotin, selenium, zinc and chromium herein.

GNC Ultra Mega Green teaches a pharmaceutical composition comprising Vitamin C (as ascorbic acid), Vitamin E (as d-alpha tocopheryl succinate), Pantothenic acid (as Calcium d-pantothenate), Niacin (as Niacinamide), Selenium (L-Selenomethionine), Chromium (hydrolyzed Protein chelate and chromium picolinate), Zinc, Vitamins B-1 (thiamin mononitrate), B-2 (riboflavin), B-6 (pyroxidine hydrochloride) and B-12 (cyanocobalamin), folic acid, and biotin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Vitamin C (as ascorbic acid), Vitamin E (as d-alpha tocopheryl succinate), Pantothenic acid (as Calcium d-pantothenate), Niacin (as Niacinamide), Selenium (L-Selenomethionine), Chromium (hydrolyzed Protein chelate and chromium picolinate), Zinc, Vitamins B-1 (thiamin mononitrate), B-2 (riboflavin), B-6 (pyroxidine hydrochloride) and B-12 (cyanocobalamin), folic acid, and biotin. It would have also been obvious to one of ordinary skill in the art to optimize the amounts of each of these vitamins and minerals.

One of ordinary skill in the art would have been motivated to employ Vitamin C (as ascorbic acid), Vitamin E (as d-alpha tocopheryl succinate), Pantothenic acid (as Calcium d-pantothenate), Niacin (as Niacinamide), Selenium (L-Selenomethionine), Chromium (hydrolyzed Protein chelate and chromium picolinate), Zinc, Vitamins B-1 (thiamin mononitrate), B-2 (riboflavin), B-6 (pyroxidine hydrochloride) and B-12 (cyanocobalamin), folic acid, and biotin because a Skilled Artisan possessing an active also possesses the salts, acids and esters of the

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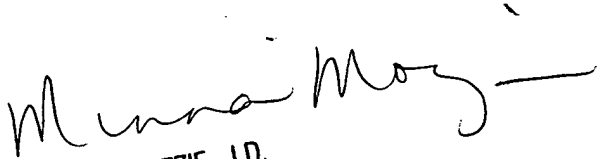
active. Employing a known salt, acid, ester of a known compound in lieu of the compound itself is within the skill of the artisan. Moreover, the Skilled Artisan would expect the salt, acid, ester of a known compound to exhibit therapeutic effects similar to those of the compound itself. Optimization of amounts is within the skill of the artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar, J.D.  
Patent Examiner  
March 6, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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